Wake Forest Baptist Medical Center	Pathology Laboratory Interim Self Inspection Procedure	Dept:	Department of Pathology
		Effective Date:	1/2/19
		Revised Date:	New
		Contact:	Laboratory Compliance Department
Name & Title: Greg Pomper, MD		Date:	1/9/19
Signature: GP			

1) **General Procedure Statement:**

a. **Purpose:** The Pathology department at Wake Forest Baptist Health strives to be in compliance with all regulations imposed by the applicable governing bodies to which each area of our laboratories is accredited. In order to ~~hold up~~ uphold these standards of care for our patients, it is mandatory that we comply with regular unannounced inspections by outside peer organizations every two years as mandated by the College of American Pathologists or (CAP). In addition to those inspections it is also mandatory for us to conduct self-inspections of our laboratories held in the off years of our inspection cycle. These exercises serve many purposes within our department, including the education of residents and staff to the laboratory inspection process and helping our laboratories to keep up with changing regulations to maintain compliance. The Pathology department retains records of the self-inspection, as well as the corrective actions for any deficiencies found as part of our quality management program.

b. **Responsible Department/Scope:**
   i. Procedure owner/Implementer: Department of Pathology
   ii. Procedure prepared by: Department of Laboratory Compliance, Quality and Safety
   iii. Supervision: CLIA Laboratory Director, Laboratory Compliance
   iv. Implementation: Department of Pathology Laboratories, Laboratory Compliance, Section Medical Directors, Section Managers and CLIA Laboratory Director

2) **Procedure:**

- Once the Self -inspection packet is received from CAP, the Pathology Department has 60 days to complete and return the summary to CAP.
- To begin this task the CLIA Laboratory Director and the Laboratory Compliance Officer select a team comprised of residents, section managers, and members of the Laboratory Compliance Section, to conduct a mock inspection of all of the laboratory sections within the Pathology Department.

- All inspection team members participating in the mock inspection are required to have completed the CAP inspection team member training.
- The team members are given 2 weeks to plan and complete the mock inspection of their assigned area.
- Findings are to be recorded on CAP deficiency or recommendation forms in the same manner as a routine inspection.
- The CLIA Laboratory Director and the Laboratory Compliance Officer will serve as the Inspection Team Leaders and points of contact for the inspectors. Any questions, concerns or standards interpretations can be brought to the Team Leads for clarification or assistance.
- At the end of the 2 weeks, the inspection team will review their finding with the CLIA Lab Director and the Laboratory Compliance Officer to simulate a mock summation preparation. At which time final inspections summaries will be prepared for return to the Section Manager.
- Within 2 days of the summary preparation, a Department wide meeting will be scheduled to include Laboratory Administration, all Section Medical Directors, Section Managers/Assistant Managers, Laboratory Compliance and as many staff as possible to present the inspection findings.
- The inspection team members will report individually on their findings, providing the Section Manager with a copy of the deficiency or recommendation forms at that time.
- At the close of the summary meeting, the Section Medical Directors and Section Managers/Assistant Managers will have 30 days to have all issues corrected and response documents completed and returned to Laboratory Compliance.
- At the end of the 30 days the CLIA Laboratory Director will review the submissions for completeness and either approve them or return them to the section for additional follow up. This process will continue until all issues are appropriately resolved to the satisfaction of the CLIA Laboratory Director.
- All information will be retained in the Laboratory Compliance Section.

3) **Review/Revision/Implementation:**

All procedures must be reviewed at least every 2 years.

- All new procedures and procedures that have major revisions must be signed by the CLIA Laboratory Director and Section Medical Director.

- All reviewed procedures and procedures with minor revisions can be signed by the designated Section Medical Director.

4) **Related Procedures: None**

5) **References: CAP standard GEN.23584**

6) **Attachments:** None

7) **Revised/Reviewed Dates and Signatures:**

8) Review Date	Revision Date	Signature